

REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Upon entry of the amendments, this application will contain claims 1-45 pending and under consideration. Preliminarily regarding claim amendments, independent claims 1, 16, 31, and 42 have been amended to introduce "compliant." Support for these amendments is found in the original claims and throughout the specification. Independent claims 26 and 30 and dependent claim 29 have been amended to require that the at least one extension be attached to the biocompatible material. Support for these amendments is found both in the original claims and throughout the specification, including for example, at page 32, lines 4 through 8. Dependent claim 27 has been amended to correct an objection regarding the dependency of that claim, the proper dependency being from claim 26 instead of claim 31. These amendments to the claims thus introduce no new subject matter.

Preliminarily, regarding specification amendments, the specification paragraph at page 26, line 18 has been amended to correct a typographical error.

The Office Action states an objection to and certain rejections of claims. The above claim amendments have been made in hopes of expediting the allowance of the application. Allowance of the application is thus requested.

Claims 1-45 stand rejected under 35 U.S.C. 103 (a) based upon the assertion of being unpatentable over Khosravi et al.

(5,618,299) in view of Hiles et al. (WO 98/25543). In support of this rejection, the Office Action posits that "[i]t would have been obvious to one of ordinary skill in the art to combine the teaching of a medical device comprising submucosa tissue (a collagenous material), as taught by Hiles et al., to a tubular medical device as per Khosravi et al., in order to provide a material that is remodeled into host replacement tissue with site-specific structural and functional properties."

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143. "If [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP § 2143.01 (citing In re Gordon, 221 USPQ 1125 (Fed. Cir. 1984)). Because a motivation to combine reference teachings or modify a reference is needed to establish a case of *prima facie* obviousness, in the absence of such motivation, no *prima facie* case of obviousness exists. See, MPEP § 2143.

With respect to claims 1-25 and 31-45, each of these claims now requires a compliant biomaterial. The devices disclosed in Khosravi et al. appear to require a relatively rigid material that

creates a biased ratcheting or locking action upon expansion of the device within the vascular lumen. The rigidity of the stent devices in Khosravi et al. is evidenced from the following two passages. First, at column 3, lines 56-63, Khosravi et al. states that stent material "provides for increased tensile strength, stiffness, and resistance to radial compression. Additionally, at column 6, line 5, Khosravi et al. states that "[t]he stent is configured so it inherently tends to roll up into a smaller diameter, but is prevented from doing so by the interlocking teeth."


Hiles et al. discloses a naturally derived compliant submucosa material. The rigidity required in the stent devices of Khosravi et al. to resist the radial forces against locking teeth is in contravention with the compliant submucosa material in Hiles et al. In other terms, the proposed modification of using the Hiles et al. submucosa material in the Khosravi et al. stent devices would make the Khosravi et al. devices unsatisfactory for use as a stent. Therefore, there is no suggestion or motivation to combine the reference teachings and the cited references do not render the present inventive embodiments obvious. See, MPEP § 2143. Withdrawal of the rejection is therefore solicited.

With respect to claims 26-30, each of these claims now requires that the at least one extension be attached to the biocompatible material. The stent devices disclosed in Khosravi et al. maintain their deployed cross-sectional diameter with the use of mechanically interlocking teeth. There is no teaching or disclosure whatsoever of attaching an extension to an underlying surface of biocompatible material, as claimed. Such inter-locking

teeth securement methods in Khosravi et al. in fact teach away from any need for the attachment feature as claimed. Moreover, there is no teaching in the Hiles et al. reference regarding making tubular constructs with an attached extension as claimed. Accordingly, the combined reference teachings do not render the present claimed embodiments obvious. See, MPEP § 2143. Withdrawal of this rejection is therefore solicited.

In view of the foregoing, it is believed that this application is in condition for allowance containing claims 1-45. The Examiner is invited to telephone the undersigned attorney if there are questions about this submission or other matters that may be handled in that fashion to expedite the present prosecution.

Respectfully submitted,

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